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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/313,625	05/18/1999	GARY D. HODGEN	P/1890-200(D)	4150

7590

09/15/2003

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/15/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/313629

Applicant(s)

HODGEN

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 6/5/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above claim(s) 3-9, 11, 14-20 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 2, 10, 12, 13 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10, 12, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Rodriguez et al.

Young et al teach antiestrogens for treating estrogen deficiency (Abstract).  
Clomiphene is specified (example 1).

Rodriguez et al teach that clomiphene treatment has been associated with an increased risk of ovarian cancer (column 2 lines 20-23). Administration of progestin products to prevent development of ovarian cancer is disclosed (abstract). L-norgestrel is specified (column 10 line 13).

It would be obvious to one of ordinary skill to add Levonorgestrel to the treatment of estrogen deficiency with clomiphene of Young et al to achieve the beneficial effect of preventing development of ovarian cancer in view of Rodriguez et al.

Applicants argue that there is no teaching of side effects for the SERM. However, as cited above, clomiphene treatments are known in the art to include an increased risk of cancer. This teaching in Rodriguez et al provides the motivation to combine. That is, the motivation to combine need not be found in the primary reference. As to Rodriguez distinguishing their treatment from HRT, such a distinction is irrelevant here, and Rodriguez is only being cited for its teachings <sup>gr</sup>reading the known <sub>AA</sub> risk of ovarian cancer with clomiphene treatment and that progestin treatment prevents

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the development of that cancer. In other words, the motivation to combine is not to use progestin<sup>s</sup> as an additional HRT agent but to ameliorate<sup>e</sup> the risk of treatment employing the HRT agent clomiphene in the primary reference. Motivation is provided, contrary to the allegation of *hindsight*

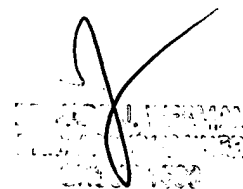
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
August 27, 2003



EDWARD WEBMAN  
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